International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 02N-0276 - Section 305: Bioterrorism Preparedness; Registration of Food Facilities

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) is submitting these comments on implementation of Section 305 of Public Health Security and Bioterrorism Preparedness and Response Act of 2002. IDFA's comments on the administrative detention provisions are submitted on its own behalf, and on behalf of its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute which represent approximately 850 members who operate more than 1550 processing facilities and produce eighty-five percent of all dairy products consumed in the United States.

In general, IDFA strongly supports the provisions of the Act, an important statute that includes provisions to enhance the security of the food supply. IDFA also supports FDA's critical role of ensuring the safety and wholesomeness of the American food supply and maintaining consumer confidence. In addition to support for the Act's mission, dairy processors offer the following comments and suggestions on Section 305 - Registration of Food Facilities. To assist FDA in the promulgation process, IDFA raises the following issues:

1. What constitutes a facility?
2. What information needs to be provided to FDA about the facility?
3. Who has access to the facility's information?
4. What are the updating requirements and how will they be performed?
5. Will FDA utilize any specific methodology in the assignment of registration numbers?

1250 H Street, N.W., Suite 900, Washington, DC 20005
telephone: 202-737-4332 fax: 202-331-7820

Issue #1 – What constitutes a facility?

A reasonably straightforward question on its face, but one that presents a few idiosyncrasies which should be addressed or clarified during the promulgation process.

IDFA notes that the Environmental Protection Agency (EPA) has for many years had to deal with the issue of what precisely constitutes a facility under the Emergency Planning and Community Right To Know Act (EPCRA) of 1986, section 313. EPA's position is that a facility is a broadly inclusive term. In fact, under EPA's interpretation, non-processing buildings (or facilities) are cumulatively grouped with processing facilities and the entire grouping is then given the designation of a "facility." EPA achieves this designation with the use of two concepts, *multi-establishment facilities* and *auxiliary facilities*. In fact, two buildings in completely separate geographic locations of a town or a city can be designated to be the same facility.

IDFA has found that the discretion offered by EPA under EPCRA has been quite helpful in allowing the regulated entity to determine how they should characterize the reporting facility and would encourage FDA to allow for similar flexibility.

The collective methodology of registering facilities could be especially important in light of uncertainty and ambiguity associated with the need to register a host of buildings that may or may not have been intended to be covered by regulation. For example, did Congress whether the Act includes auxiliary facilities, such as company headquarters where manufacturing, processing, packaging and holding activities are not taking place, storage and transfer facilities (for example milk transfer stations, and grain elevators) and any number of other collection and transfer buildings must be registered as facilities. If FDA intends to include those auxiliary facilities, IDFA strongly urge that FDA allow them to be covered by inclusion as indicated above.

In a related matter, IDFA would also encourage FDA to allow for registration to be done on a facility, division or corporate wide basis at the discretion of the regulated entity. For example, personnel at company headquarters should be permitted to register all facilities within their company if they so choose or delegate that responsibility to personnel at the individual facilities that make up the company.

Issue #2 -- What information needs to be provided to FDA about the facility?

The statutory language specifies very little information that needs to be collected. Specifically, the statute calls for the name and address of the facility and all trade names under which the registrant conducts business, and if determined necessary by the Secretary, the general food category. Dairy processors are ready and willing to provide FDA with that information. We would urge FDA to allow for registering and updating that information on the worldwide web.

In addition to the aforementioned minimal information that is required by statute, IDFA and dairy processors envision that at least a few additional informational items are

necessary to develop, maintain and update a workable list as required by Congress. To that end, we would suggest that FDA also require a contact either by name or title, at the registrant's discretion and telephone information. Beyond that, dairy processors would also like to have the option to update their information online and are willing to provide additional information, as necessary, to provide for secure access to that information.

Further, dairy processors have suggested that such a secure online system allow for multiple users to access that information from the registering facility. We recommend that an online system provide for at least two users and the appropriate amount of additional information to permit a reasonable level of security.

IDFA believes that the quantity and types of information items collected under the registration requirements end here. IDFA is aware of an intention by FDA to utilize the registration information as a method to contact appropriate facilities in the event FDA acquires information from law enforcement officials or the intelligence community that could impact a facility. IDFA feels that such intentions, while well meaning, are best handled through established security systems such as the Information Sharing and Analysis Center (ISAC) housed at the FBI's National Infrastructure Protection Center (NIPC). The government and the food industry have already set up the Food ISAC and the communication channels are currently functioning. Duplicating what is currently in place is not logical given today's shortage of resources at FDA and elsewhere, especially in light of the enormous new mandate's in the Act.

On a tangential issue to the above, we are somewhat concerned that there is some confusion and misunderstanding about trade names and brand names. It appears some individuals are not aware that trade names are the names that businesses operate under, otherwise known as "doing business as" or dba's. Brand names, on the other hand, are the names that are used for labeling and marketing products. IDFA recommends that FDA dispel that confusion when the proposed regulation is published. The statute does not authorize FDA to collect brands names; no one should be mislead into thinking it does.

Issue #3 -- Who has access to the facility's information?

It is our understanding that FDA has stated that its belief is that the registration number issued by FDA to a registrant is not to be disclosed to the public or any other person other than the registrant and appropriate authorized government officials.

IDFA would assert that any and all the information that is required under the Act is not intended for disclosure to the public and the purpose of the Act is largely defeated by allowing public access. The Act's overriding purpose is enhancing security, not expanding the public's or the community's right-to-know. Security and law enforcement by their very nature require information to be discretely and judiciously used, it would be inappropriate to allow access to and the use of facility information collected under the Act by the public. IDFA encourages FDA to assert that position in the regulation it proposes.

Issue #4 -- What are the updating requirements and how will they be performed?

IDFA anticipates the need to update registration information from time to time as deemed by changes in business circumstances. To facilitate the industry's ability to keep FDA as up to date as possible, IDFA again encourages FDA to allow for online access to a registrant's information, by the registrant and an additional person, or two, as designated by the registrant for the purpose of updating the required information in an expeditious manner.

With regard to timing for updates, IDFA would suggest avoiding an unnecessary complexity by mandating specific timetables. IDFA believes that FDA should require the information to be updated within a reasonable amount of time. If updating can be achieved online, IDFA has no reason to believe that facilities or companies will not do so in a reasonable manner.

The other option, which we do not feel is necessary or appropriate, is for FDA to mandate that a facility must update its records within specific number of days after significant changes occur.

Issue #5 -- Will FDA utilize any specific methodology in the assignment of registration numbers?

Because IDFA believes that any and all information created and gathered under the Act should be kept confidential, IDFA's only recommendation in this area is that whatever system FDA creates or adopts be based upon established, well-planned and organized concepts that will be helpful to FDA. FDA should consider a system that utilizes several useful schemes, which combined, would provide FDA with robust information. For example, FDA's system could be based on three elements.

The first element is a facility's North American Industry Classification System (NAICS) number, a numeric system that provides more information as digits are added. It is replacing the older Standard Industrial Classification (SIC) code system and for example, dairy product manufacturing carries a NAICS code of 3115, cheese manufacturing, a subset of dairy manufacturing, carries a NAICS code of 311513.

The second element is a numeric two-digit code that corresponds to a specific state. This element is already a concept that is in use in many states and by other federal agencies, such as The Department of Agriculture (USDA) in its plant coding system. Additional digits may need to be incorporated to accommodate foreign registrations.

The third element could be FDA's own proprietary code to provide FDA with information it needs to isolate the facility to a single entity. By example, the combination of the three elements NAICS + State Code + FDA code could result in a facility identification number enabling FDA personnel to identify quickly the type and location of the plant.

IDFA appreciates the opportunity to comment on the regulatory process involving Section 305 of the Act, and stands ready to answer any questions to help achieve these important objectives of this section.

Sincerely,

Clay Detlefsen
Vice President, Regulatory Affairs & Counsel